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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/384,811	08/27/99	LEMAUX	P 18941000710U

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EXAMINER

COLLINS, C

ART UNIT PAPER NUMBER

1638

DATE MAILED: 09/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/384,811

Applicant(s)

LEMAUX ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The Amendment filed June 29, 2001, paper no.9, has been entered.
2. Claims 1 and 9 have been newly amended.
3. Claims 1-16 are pending.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Newly amended claim 1 is rejected, and original claims 2-8 remain rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous office action.
6. Applicant's traversal of the claim rejections made under 35 U.S.C. 112, first paragraph, is acknowledged.
7. Applicant argues that the written description requirement does not demand a detailed description of that which is known to one of ordinary skill in the art, that the structural and physical features of Ac and Ds elements are well known in the art, that the claims do refer to a structural and physical feature of the transgenic plants in that the designations Ac element and Ds element provide information about the structural identity of these elements, and that the rejection misapplies *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997).
8. Applicant's arguments have been fully considered but they are not persuasive.

9. Although the structural and physical features of Ac and Ds elements are well known in the art, the structural and physical features of barley plants comprising Ac and Ds elements are not. Given the size and complexity of the barley genome, transposable elements such as Ac and Ds will insert in a variety of different chromosomal locations, resulting in a variety of different phenotypic effects in the resultant transgenic plants. The Examiner maintains that *Lilly* is correctly applied in the instant case because the physical or structural characteristics of the claimed products, namely transgenic barley plants comprising Ac and Ds elements, are not described in the specification in such a way as to convey to one skilled in the art that the inventor(s) had possession of the claimed genus of invention.

10. Accordingly, Applicant's arguments are not persuasive.

Claim Rejections - 35 USC § 102

11. The rejection of claims 9, 11, and 12 under 35 U.S.C. 102(b) as being anticipated by McElroy et al. is withdrawn in light of Applicant's amendment of claim 9.

Claim Rejections - 35 USC § 103

12. Newly amended claims 1 and 9 are rejected, and original claims 2-8 and 10-14 remain rejected, under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. in view of Wan et al. and Bancroft et al., for the reasons of record set forth in the previous office action.

13. Claims 15-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McElroy et al. in view of Wan et al., in view of Bancroft et al., and further in view of Perera et al., for the reasons of record set forth in the previous office action.

14. Applicant's traversal of the claim rejections made under 35 U.S.C. 103(a) is acknowledged.

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15. Applicant argues that the rejection has not established that the teachings of McElroy et al., Wan et al., and Bancroft et al. could be combined with a reasonable expectation of success, that the prior art of Izawa et al. teaches away from applying an Ac/Ds transposon system to barley, and that, based on the prior art of Izawa, there was no motivation for one of skill to combine the references.

16. Applicant's arguments have been fully considered but they are not persuasive.

17. Claims 1-16 do not recite any specific limitations that clearly teach over the prior art of McElroy et al., Wan et al., Bancroft et al., and Perera et al. The claims do not elucidate what Applicant did differently from McElroy et al., Wan et al., and Bancroft et al. The Examiner maintains that the success of Wan et al. in transforming barley, and the success of McElroy et al. in demonstrating Ac transposase-mediated excision of Ds in barley cells, would motivate one of skill in the art to combine the teachings of the teachings with a reasonable expectation of success. The success of Bancroft et al. in using the Ac and Ds transposable elements in another heterologous plant transformation system would provide further motivation to combine the teachings.

18. The Examiner disagrees that the high frequency of Ds excision in the heterologous monocot rice, observed by Izawa et al., teaches away from using an Ac/Ds transposon tagging system in the heterologous monocot barley. Izawa et al. also teach that the frequency of Ds transposition has been reported to vary from species to species, and that it was known in the art that level of Ac transposase can affect the frequency of Ds element excision (page 222 column 1 second full paragraph). McElroy et al. teach that Ac dosage effects vary depending on the system in which Ds transposition is being monitored, and that efficient Ds excision in the heterologous

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monocot barley appears to be inversely proportional to Ac dosage, as is the case for the homologous monocot maize (page 162, column 2, first full paragraph). Given that the Ac transposase of Izawa et al. was expressed under the control of the strong constitutive CaMV 35S promoter, and given that efficient Ds excision in two other monocot systems appears to be inversely proportional to Ac dosage, the Examiner maintains that Izawa et al. teaches away from using a high dosage of Ac transposase for Ac/Ds transposon tagging in monocot systems in general.

19. Accordingly, Applicant's arguments are not persuasive.

Claim Rejections - 35 USC § 101

20. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

21. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

22. The claims are drawn to transgenic barley plants comprising Ac and Ds transposable elements.

23. The claimed transgenic barley plants are not supported by a specific asserted utility because the disclosed use of Ac and Ds transposable elements to transform barley plants is generally applicable to the use of any type of transposable element to transform any species of plant, and therefore is not particular to the products claimed. The claimed transgenic barley plants are not supported by a substantial asserted utility because no particular phenotypic attributes for any of the claimed plants have been established. There is no specific or substantial

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use for transgenic barley plants that comprise Ac and Ds transposable elements. It would require additional research to establish the utility of the claimed transgenic barley plants.

24. Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
September 4, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800

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